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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/585,546

03/02/2009

Marcin Krotkiewski

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20676

7590

03/14/2011

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EXAMINER

HOFFMAN, SUSAN COE

ART UNIT

PAPER NUMBER

1655

MAIL DATE

DELIVERY MODE

03/14/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,546	Applicant(s) KROTKIEWSKI, MARCIN	
	Examiner Susan Hoffman	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 4,9-16 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-8 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed January 14, 2011 has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action. Any rejection set forth in a previous Office action that is not specifically set forth below is withdrawn.
2. Claims 1-18 are pending.
3. In the reply filed on August 16, 2010, applicant elected Group I, claims 1-8 and 17 and the extraction of claim 3 for the species with traverse.
4. Claims 4, 9-16 and 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim.
5. Claims 1-3, 5-8 and 17 are examined on the merits.

Claim Objections

6. Claims 1 and 17 are objected to because of the following informalities: "catechins" is misspelled as "catachins". Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. Claims 1-3, 5-8 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite because it is unclear what metabolic rates are encompassed by "low" metabolic rates.

Claim Rejections - 35 USC § 103

8. Claims 1, 3, 5-8 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liao (US 6,610,749), Majeed (US 5,804,596), Gow (US 7,279,184), de la Harpe (US 6,251,888), and BE 1009545 for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that none of the references teach a *Coleus forskohlii* extract containing at least 10% by weight of diterpene forskohlin as recited in claim 1. However, Majeed specifically teaches a composition comprising forskohlin extracted from *C. forskohlii*. The extract can contain from about 15% to 100% forskohlin (see column 6, lines 16-27). Forskohlin is a type of diterpene. Thus, Majeed is considered to teach a *C. forskohlii* extract with at least 10% by weight of diterpene forskohlin.

Applicant also argues that the claimed invention is patentable over the prior art because Figures 2A and 2B show that the composition produces synergistic results. Applicant argues that Figure 2A shows that each individual ingredient results in an increase in body weight from 42 to 46% while the results for the combined ingredients show an increase of 32%. Applicant also argues that Figure 2B shows that each individual ingredient results in a 71 to 79% change in body weight while the results for the combined ingredients show a change of 60%. Applicant states that these results show that the claimed composition produces synergistic results. However, applicant has not supported the assertion that these results are synergistic rather than additive (see MPEP section 716.02 (a)). An artisan of ordinary skill would clearly expect a combination of five weight loss ingredients to function in an increased manner in comparison with one weight loss ingredient. Thus, the showing that the combination of the five ingredients

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functions better than the single ingredient is not considered to be unexpected. In addition, the results shown in Figures 2A and 2B are not considered to be commensurate in scope with the claimed invention. This is because the results are only shown for one formulation that falls within the claimed percentages while the claims encompass numerous other embodiments that are not used to produce the experimental data (see MPEP section 716.02 (d)).

In addition, applicant argues that "There is no basis for concluding predictability where a composition includes five different constituents, each present in the composition in specific and varying amounts...each of which is mentioned in a different reference..." because it would require limitless numbers of optimizations to arrive at the claimed compositions. However, the cited prior art specifically teaches that each of the claimed ingredients was known in the art at the time of the invention to be useful to treat obesity. The fact that the claimed ingredients might be among numerous other agents suitable for treating obesity does not negate the cited references' explicit teachings suggesting that the claimed ingredients would have been useful for that treatment. The fact that the combination is one of a number of obvious combinations of obesity treatments does not make it any less obvious. Thus, the combination of the prior art is considered to properly teach combining the claimed ingredients together into a single composition. In addition, in regards to the amounts of each ingredient in the composition, . "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The references teach that each of the claimed ingredients is a pharmaceutically active ingredient. An artisan of ordinary skill would routinely

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modify the amount of pharmaceutically active ingredients based on the patient's age, weight, gender, and condition.

9. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liao (US 6,610,749), Majeed (US 5,804,596), Gow (US 7,279,184), de la Harpe (US 6,251,888), and BE 1009545 as applied to claims 1, 3, 5-8 and 17 above, and further in view of Chokshi (US 2003/0059403) for the reasons set forth in the previous Office action.

Applicant does not set forth any specific arguments regarding this rejection. Thus, this rejection is considered valid for the reasons discussed above and in the previous Office action.

10. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hoffman whose telephone number is (571)272-0963. The examiner can normally be reached on Monday-Thursday, 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hoffman/
Primary Examiner, Art Unit 1655